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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,333	03/06/2002	Paz Einat	EINAT1.1D	1554

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
ASHEN, JON BENJAMIN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,333	EINAT ET AL.	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-23* is/are pending in the application.

4a) Of the above claim(s) *12-16 and 24-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/6/02; 12/31/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 17-23, in the reply filed on 10/28/04 is acknowledged. The traversal is on the ground(s) that Groups II and III should be examined together because the therapeutic utility is the only practical utility for the RNA of group II and therefore a full and proper search for the RNA would include a search of therapeutic methods of use thereof. This is not found persuasive for the reasons provided on page 5, section 4 of the prior Office Action mailed 9/30/04, which sets forth another practical utility for the invention of group II. In regards to Applicants assertion that a full and proper search for the RNA (the invention of group II) would include a search of therapeutic methods of use thereof, it is respectfully pointed out to Applicant that despite their assertion, a full and proper search for the RNA would not be coextensive with a search of therapeutic methods of use thereof as set forth page 5, section 4 of the prior Office Action mailed 9/30/04. Applicants traversal of the restriction between the inventions as set forth in Groups I and III is considered moot in light of Applicant's election of the invention of Group II. Applicant's assertion, on page 6 of the communication filed 10/28/04 that certain process claims should be rejoined with the product claims of claims 17-23 if the latter should be found allowable is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Status of the Application

2. Claims 17-23 are pending and currently under examination in this application. Claims 12-16 and 24-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/28/04.

Information Disclosure Statement

3. The PTO form 1449 (IDS) filed on 03/06/02 has only been considered in part for the following reasons. Applicants have requested that the documents listed on the aforementioned IDS, that were filed in prior applications 09/138,112 and 09/604,978, be considered and made of record in accordance with 37 CFR 1.98(d). However, only references BS, BU and CM from the above mentioned IDS were found in the prior application files. Therefore, only these references have been considered. Should applicant desire that the remainder of the references listed on the above mentioned IDS be considered and made of record, Applicant is requested to submitt copies of those references. The IDS filed 12/31/2002 has been fully considered in this application.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 20 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 20 and 22, were newly presented in this Application in the amendment filed 03/17/04. Claim 20 is drawn to an RNA molecule that targets mRNA encoding a polypeptide having the amino acid sequence of SEQ ID NO: 10 that is an antisense RNA molecule. Claim 22 is drawn to an RNA molecule that targets DNA encoding a polypeptide having the amino acid sequence of SEQ ID NO: 10. Applicant has pointed to pages 23-27 as support for the limitations set forth in new claims 20 and 22. However, although support for new claims to RNA molecules that are ribozymes was located, no support could be found for new claims to an RNA molecule that is an antisense RNA or for an RNA molecule that targets DNA. If applicant believes that such support is provided by the specification as filed, applicant should point out, with particularity, where such support is to be found.

Claim Rejections - 35 USC § 102 or 35 USC § 103

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.A person shall be entitled to a patent unless -

7. Claims 17-20 and 22-23 are rejected under 35 U.S.C. 102(e) or 35 USC 103(a) as being anticipated by or obvious over Chang (U.S. Patent 5,912,326). The instant invention as set forth in claims 17-20 and 22-23 is an RNA molecule which targets mRNA encoding a polypeptide having the amino acid sequence of SEQ ID NO: 10 (claim 17) wherein the targeting prevents processing, splicing, transport or translation of the mRNA (claim 18) or results in mRNA degredation (claim 19) wherein the RNA molecule is an antisense RNA (claim 20) that also targets DNA encoding a polypeptide having the amino acid sequence of SEQ ID NO: 10 (claim 22) wherein the targeting results in a transcriptionally inactive product (claim 23).

In the instant case, the the meaning of the terms "targets" and "targeting" as recited in the above claims 17 and 22 and 18-19 and 23 respectively, could not be located in the disclosure of the specification as filed. Therefore, these terms have been given their broadest reasonable interpretation and, for the purposes of prior art, are interpreted to mean any RNA molecule that shares sufficient complementarity with another nucleic acid molecule such that hybridization under any conditions would occur. The following prior art is applied.

Chang discloses an oligonucleotide of SEQ ID NO: 15 that is 84.2% identical to the nucleic acid sequence (mRNA and DNA) encoding the polypeptide of SEQ ID NO: 10 of the instant invention. The 5' end of the 19 nucleobase oligonucleotide of Chang

is 100% identical, over the first 16 contiguous nucleobases, to the polypeptide of SEQ ID NO: 10 of the instant invention. Chang discloses that the term nucleic acid refers to both DNA and RNA and should be understood to include analogs of either RNA or DNA made from nucleotide analogs and, as applicable to the embodiment being described, single (sense or antisense) and double stranded polynucleotides (col. 10, lines 61-67). Chang also states that "Another aspect of the invention relates to the use of the isolated nucleic acid in "antisense" therapy. As used herein, "antisense" therapy refers to administration or in situ generation of oligonucleotide probes or their derivatives which specifically hybridizes (e.g. binds) under cellular conditions, with the cellular mRNA and/or genomic DNA encoding a cdGF protein so as to inhibit expression of that protein, e.g. by inhibiting transcription and/or translation. The binding may be by conventional base pair complementarity, or, for example, in the case of binding to DNA duplexes, through specific interactions in the major groove of the double helix. In general, "antisense" therapy refers to the range of techniques generally employed in the art, and includes any therapy which relies on specific binding to oligonucleotide sequences. An antisense construct of the present invention can be delivered, for example, as an expression plasmid which, when transcribed in the cell, produces RNA which is complementary to at least a unique portion of the cellular mRNA which encodes a cdGF protein. Alternatively, the antisense construct is an oligonucleotide probe which is generated *ex vivo* and which, when introduced into the cell causes inhibition of expression by hybridizing with the mRNA and/or genomic sequences of a cdGF gene (col. 16, lines 28-47). The oligonucleotide of Chang would therefore be an RNA

molecule targeted to the mRNA or DNA encoding the polypeptide of SEQ ID NO: 10 of the instant invention and, absent evidence to the contrary, function as an antisense RNA capable of mediating mRNA degredation, thereby preventing processing, splicing, transport and translation of the targeted mRNA and as a result, producing a transctiptionally inactive product.

Furthermore, since the prior art oligonucleotide of Chang meets all the structural limitations of the claims, the prior art oligonucleotide comprises an antisense RNA that is targeted to an mRNA or DNA encoding a polypeptide having the amino acid sequence of SEQ ID NO: 10, absent evidence to the contrary. See, for example, MPEP § 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Therefore, the instant invention is anticipated or obvious over Chang (U.S. Patent 5,912,326).

8. Claims 17-20 and 22-23 are rejected under 35 U.S.C. 102(a) or 35 USC 103(a) as being anticipated by or obvious over Sutcliffe et al. (W0 98/05352). The invention as set forth in claims 17-20 and 22-23 is outlined in a previous rejection herein. Sutcliffe et al. disclose SEQ ID NO: 16 that is 20 nucleobases in length and 100% identical to the nucleic acid sequence (the mRNA or the coding DNA) encoding the polypeptide of SEQ ID NO: 10 of the instant invention. Sutcliffe et al. disclose that a nucleic acid is any polynucleotide or nucleic acid fragment whether it be a polyribonucleotide or polydeoxyribonucleotide, i.e., RNA or DNA or analogs thereof (pg. 23, lines 8-10) and that nucleic acid molecules of their invention that are isolated nucleic acid molecules that are preferably single stranded oligonucleotides and that "Nucleic acid-based inhibtion is well known and generally referred to as antisense technology by virtue of the use of nucleotide sequences having complementarity which can hybridize to the sense strand or mRNA and thereby perturb gene expression" (pg 27, section 4, "Inhibitory nucleic acids"). Sutcliffe et al. also disclose that the oligonucleotides of their invention function as antisense oligonucleotides wherein they state that "oligonucleotides are described herein which are complementary to mRNA that encodes a hypocretin protein of this invention and that are useful for reducing gene expression and translation of the hypocretin mRNA, thereby altering hypocretin levels in a tissue" (pg. 62, lines 24-27). Sutcliffe et al. further disclose the use of nucleic acids of their invention for inhibiting gene expression comprising contacting cells or tissues with a therapeutically effective amount of a pharmaceutically acceptable composition comprising a DNA segment of their invention (pg. 65, section b. "Methods for Inhibiting Gene Expression").

Furthermore, since the prior art oligonucleotide of Sutcliffe et al. meets all the structural limitations of the claims, the prior art oligonucleotide comprises an antisense RNA that is targeted to an mRNA or DNA encoding a polypeptide having the amino acid sequence of SEQ ID NO: 10, absent evidence to the contrary. See, for example, MPEP § 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Therefore, the instant invention is anticipated or obvious over Sutcliffe et al. (W0 98/05352).

9. Claims 17-23 are rejected under 35 U.S.C. 102(e) or 35 USC 103(a) as being anticipated by or obvious over Pavco et al. (U.S. Patent 6,818,447). The invention as set forth in claims 17-20 and 22-23 is outlined in a previous rejection herein. Claim 21 is drawn to the RNA molecule of claim 17 that is a ribozyme. Pavco et al. disclose a RNA molecule that is a hammerhead ribozyme of SEQ ID NO: 7749, the binding arms

of which target (with 94.1% complementarity including the first 5 nucleobases from the 5' and 3' end of each binding arm, thus indicating that sufficient binding for mRNA degradation would occur by complementary binding of each binding arm) the nucleic acid sequence (the mRNA or the coding DNA) encoding the polypeptide of SEQ ID NO: 10 of the instant invention (cols. 129-130, Table VIII). Therefore, the ribozyme of Pavco et al. is an antisense RNA molecule that targets mRNA encoding a polypeptide having an amino acid sequence of SEQ ID NO: 10 wherein the targeting would prevent processing, splicing, transport or translation of the mRNA and would result in a transcriptionally inactive product. The ribozyme of Pavco et al., in being complementary to a nucleic acid sequence, will target all complements of that sequence, be they mRNA or the DNA encoding that mRNA.

Furthermore, since the prior art ribozyme of Pavco et al. meets all the structural limitations of the claims, the prior art ribozyme comprises an antisense RNA that is targeted to an mRNA or DNA encoding a polypeptide having the amino acid sequence of SEQ ID NO: 10, absent evidence to the contrary. See, for example, MPEP § 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product,

apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Therefore, the instant invention is anticipated or obvious over Pavco et al. (U.S. Patent 6,818,447).

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Soares et al. (U.S. Patent 5,846,721).

Monia et al. (U.S. Patent 6,410,518).

Stinchcomb et al. (U.S. Patent 6,194,150).

Eckstein et al. (U.S. Patent 6,656,731).

Stinchcomb et al. (U.S. Patent 5,807,703).

Pavco et al. (U.S. Patent 6,346,398).

Beigelman et al. (U.S. Patent 6,617,438).

Zwick et al. (U.S. Patent 6,350,934).

Lu (U.S. Patent 6,682,930).

Conclusion

11. No claims currently under examination in this application are in condition for allowance or free of the prior art searched.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jba